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|-------------------------------|-----------------|-----------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 08/836,576 | HAENSLER ET AL. | |
| | Examiner | Art Unit | |
| | Zachariah Lucas | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to the papers filed on December 23, 2003.
 - The allowed claim(s) is/are 28, 30, 33-37, 62-69, 75-82, 87 and 88.
 - The drawings filed on _____ are accepted by the Examiner.
 - Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - All
 - Some*
 - None
 - Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. _____.
 - Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
 - Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - The translation of the foreign language provisional application has been received.
 - Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**
- A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 - CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - hereto or 2) to Paper No. _____.
 - including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

- DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>1-12-2004</u> |
| <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | <input type="checkbox"/> Other |

DETAILED ACTION

Status of the Claims

1. Claims 28, 30-37, 61-69, and 75-88 were pending and under consideration in the application upon the mailing of the prior action on March 26, 2003. All claims were rejected in that action. In the Response (filed on September 26, 2003) and the supplemental response (filed on November 21, 2003) claims 31, 32, 83-86, were cancelled, claims 30, 36, 37, 75, 80-82, were amended, and claims 89-94 were added. Claims 28, 30, 33-37, 62-69, 75-82, 87 and 88 are allowed.

Specification

2. **(Prior Objection-Withdrawn)** The disclosure was objected to in the prior action because of the following informalities: In the chart on page 15 of the application, the first identified composition appears to include negative 15 µg of HA, and 0 (mg) of DC-Chol. It was unclear what is meant by “- 15 µg.” In view of the amendment of the application, the objection is withdrawn.

Claim Objections

3. **(Prior Objection- Withdrawn)** Claims 28, 30-37, 62-69, and 75-88 were objected to because of the following informalities: Claim 30 was amended in Amend. E to read on a vaccine composition to read on a vaccine composition comprising 3-E-(N-(N-N'-dimethylaminoethane)carbamoyl) cholesterol. In view of the amendments to the claims correcting the language, the objection is withdrawn.

4. **(Prior Objection- Withdrawn)** Claim 31 was objected to because it is not further limiting of the claim from which it depends. In view of the cancellation of the claim, the objection is withdrawn.

5. **(Prior Objection- Withdrawn)** Claim 32 was objected to because it is not further limiting of the claim from which it depends. In view of the cancellation of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 112

6. **(Prior Rejections- Withdrawn)** In view of the amendments to the claims, the outstanding rejections under 35 U.S.C. 112 are hereby withdrawn.

Claim Rejections - 35 USC § 103

7. **(Prior Rejections- Withdrawn)** In view of the Applicant's arguments in traversal, the outstanding rejections of the claims under 35 U.S.C. 103(a) as being unpatentable over Bolcsak et al, U.S. Patent 5,100,662, in view of Gao et al., Biochem. Biophys. Res. Comm., 179: 280-285; over Popescu et al., EPA 0 356 339, in view of Epand et al., U.S. Patent 5,283,185; or over either Bolcsak et al. in view of Gao et al., or Popescu et al., in view of Epand et al., and further in view of del Prete et al., Trends in Microbiol, 2(1): 4-6 are withdrawn.

EXAMINER'S AMENDMENT

8. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR

1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael S. Greenfield on January 12, 2004.

The application has been amended as follows:

Claims 89-94 have been cancelled from the application.

Claims 89 and its dependant claims are cancelled as redundant to the understood definition of the term antigen as provided in the specification.

Claims 90 and its dependant claims are cancelled as lacking adequate support in the application.

9. The following is an examiner's statement of reasons for allowance: the claims are found allowable over the prior art for the reasons indicated by the Applicant, i.e., as argued by the Applicant, the term "antigen" would be understood by those in the art to exclude nucleic acids. This is because these molecules are not generally considered to be antigens that would be recognized or targeted by an immune response upon administration to a subject. As the art provides no teachings regarding the use of DC-Chol in vaccines or immunogenic compositions other than those comprising nucleic acids (DNA vaccines) the claimed invention is found allowable. Thus, while the application lacks ipsius verbis support for the language "non-nucleic acid" cancelled from claim 30, such a limitation would nonetheless have been understood part of the meaning of the term "antigen" by one of ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

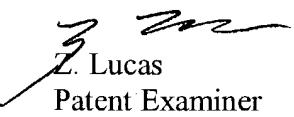
fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

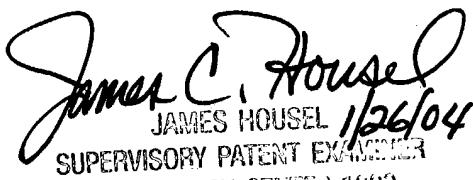
Conclusion

10. Claims 28, 30, 33-37, 62-69, 75-82, and 87-88 are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Z. Lucas
Patent Examiner
January 13, 2004


JAMES C. HOUSEL 1/26/04
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